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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,449	09/09/2003	Mark A. Reiley	29914-701.407	5178
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SHAY LAW GROUP LLP 2755 CAMPUS DRIVE SUITE 210 SAN MATEO, CA 94403			EXAMINER ISABELLA, DAVID J	
			ART UNIT 3738	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/658,449

Applicant(s)

REILEY, MARK A.

Examiner

DAVID J. ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 22 and 24-27 is/are pending in the application.
- 4a) Of the above claim(s) 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 22 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Status of the Claims

Currently claims 1-20,22,24 are pending for consideration. Claims 21 and 23 have been cancelled; and claims 25-27 remain withdrawn from consideration as being directed to an non-elected invention.

Response to Arguments

Applicant's arguments filed 12/27/2006 have been fully considered but they are not persuasive.

With respect to the outstanding rejection under 35 USC 112, applicant's representative is correct, in that, there is no claim 29. However, examiner incorrectly referenced claim 29 but more correctly should have referenced claim 20. Accordingly, the rejection under 35 USC 112 to claim 20 appears below.

Examiner acknowledges cancellation of claims 21 and 23. These claims were rejected under 35 USC 101 in the previous office action.

The rejection to the claims under 35 USC 102 over any of Wall, Zang, Homsy and Morgan as comprising each structural element as broadly claimed is maintained by the examiner. Applicant argues that the every feature recited by the claims are not disclosed by the references listed above. Examiner has reproduced claim 1 below.

1. (Original) A prosthesis to replace all or a portion of a natural facet joint on a vertebral body comprising a prosthesis body accommodating fixation to the vertebral body at or near a pedicle and without support by a lamina, the prosthesis body including a fastening element installed within the vertebral body at or near a pedicle, and an artificial facet joint structure carried

by the prosthesis body at a location spaced from the fastening element, the artificial facet joint structure being adapted and configured to replace all or a portion of a natural facet joint.

Examiner maintains as broadly worded the cited prior art independently show a prosthesis comprising a body including a fastening element that is to be installed within a bony body including an artificial facet joint structure carried by the body spaced from the fastening element where the facet joint is configured to replace all or a portion of the natural joint. The specific recitation of the prosthesis to be used to replace all or a portion of the natural facet joint on a vertebral body is not disclosed in any of the applied references. In response to applicant's argument that every feature of the claim is not met by the prior art, the examiner respectfully disagrees. Recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. It is the examiner's contention that the devices of the applied references do set forth structure that is capable of performing the intended function, i.e. a prosthesis to replace all or a portion of a natural facet joint on a vertebral body.

Claim Rejections - 35 USC § 112

Claims 2-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-4 are indefinite. It is not clear as to what frame of reference is being used to establish the location of the sub-elements of the claims. It appears applicant is attempting to define the relationship of the prosthesis with respect to the various axes of the body.

Claims 5-7 the term "adapted and configured" in the claims is a relative term which renders the claim indefinite. The term "adapted and configured" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This language absent structural features relies solely on a functional use (ie. to replace a certain anatomical feature. The elected invention is directed to figure 36. Claim 1 positively sets forth structural elements of a body and a facet joint structure. However, claim 5 fails to positively set forth structure that would function after the removal of at least some of the facet joint from the vertebral body. It is not clear from the specification, what form of modification or structure would be inherent in the device after removal of at least some of the facet joint. Since there is only one embodiment, figure 36, it is not clear how the structure of this one embodiment differs from each other as required in each of claims 5-7.

Claim 20 should be reworded in the form of a Markush group. As worded, it is not clear if each material, as cited, is present in the prosthesis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1–8,10,18,19,20,22 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by any of Zang et al (5314486), Wall [4633722], Homsy et al [4778472] and Morgan [4917701].

Each prior art individually discloses a prosthesis comprising a fastening element, and an artificial joint structure carried by the fastening element. While the prosthesis of each prior art is intended for replacement of a other type of joints, the structure as broadly claimed is fully met by each of the applied prosthesis. Each prosthesis is structurally similar to that as illustrated by applicant and therefor, examiner contends that each device is capable of performing the function of replacing all or a portion of the natural facet joint.

Claims 2-4, the claim as worded may be interpreted in the manner by which the prosthesis is attached in vivo. (ie. method of using the prosthesis, where the placement of the device would position the fastening element superior to the joint structure.)

Claim 5, in so far as definite, the placement of the prior art joint according to claim 1 would yield in a facet joint structure that articulates with a portion of the joint structure of the adjoining vertebral body.

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Claims 6, in so far as definite, the placement of the prior art joint according to claim 1 would yield in a facet joint structure that replaces a cephalad portion of the natural facet joint.

Claim 7, in so far as definite, the placement of the prior art joint according to claim 1 would yield in a facet joint structure that replaces a cephalad portion of the natural facet joint and articulate with a caudal portion of a facet joint.

Claim 8, see each joint structure in the respective prior art as applied in claim 1 supra.

Claims 10-14 and 18, see prosthesis of Zang, et al. One of the fastening element or the facet joint structure of Zang et al is illustrated to be one piece, the other of the element is shown to be formed of two pieces with a tapered connection.

Claims 19 and 20, see materials as set forth in each reference as applied in claim 1.

Claims 22 and 24, see Zang, et al wherein the prosthesis is fabricated from selected biocompatible materials including titanium, cobalt chrome and may be fastened to the bone by with roughen surface providing a bone in-growth surface medium.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8,10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zang et al as applied to claim 1 above, and further in view of Carignan, et al (4955916).

The insert of Zang et al is mechanically fixed to the fastening element. Carignan et al teaches forming each cooperating sub-elements of the total joint of plural pieces for better flexibility and adaptability to meet the structural constraints of the individual patient's bone structure. To form each sub-element of Zang et al of a multiple piece connection would have been obvious from the teachings of Carignan.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zang et al as applied to claim 1 above, and further in view of Hamilton et al (5314492).

Zang et al discloses forming one of the cooperating sub-elements of the total joint of plural pieces for better flexibility and adaptability to meet the structural constraints of the individual patient's bone structure. While Zang et al does not use adhesive in combination with the tapered connection, Hamilton et al teaches using both fixation means for providing a secure connection between the sub-elements. To add adhesive to the tapered surfaces of Zang et al to ensure a more secure connection between the two components would have been obvious to one with ordinary skill in the art from the teachings of Hamilton et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



DAVID J. ISABELLA
Primary Examiner
Art Unit 3738

DJI
8/18/2006